UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): April 28, 2021

GALERA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39114**	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2 W Liberty Blvd #100
Malvern, PA 19355
(Address of principal executive offices) (Zip Code)

(610) 725-1500
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**GRTX**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

Galera Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On April 28, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at *www.galeratx.com*. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information contained in Item 7.01 of this Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Corporate Slide Presentation of Galera Therapeutics, Inc. dated April 28, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GALERA THERAPEUTICS, INC.

Date: April 28, 2021

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
President and Chief Executive Officer

Exhibit 99.1

Transforming **radiotherapy** for patients with cancer

April 2021

Galera Therapeutics, Inc

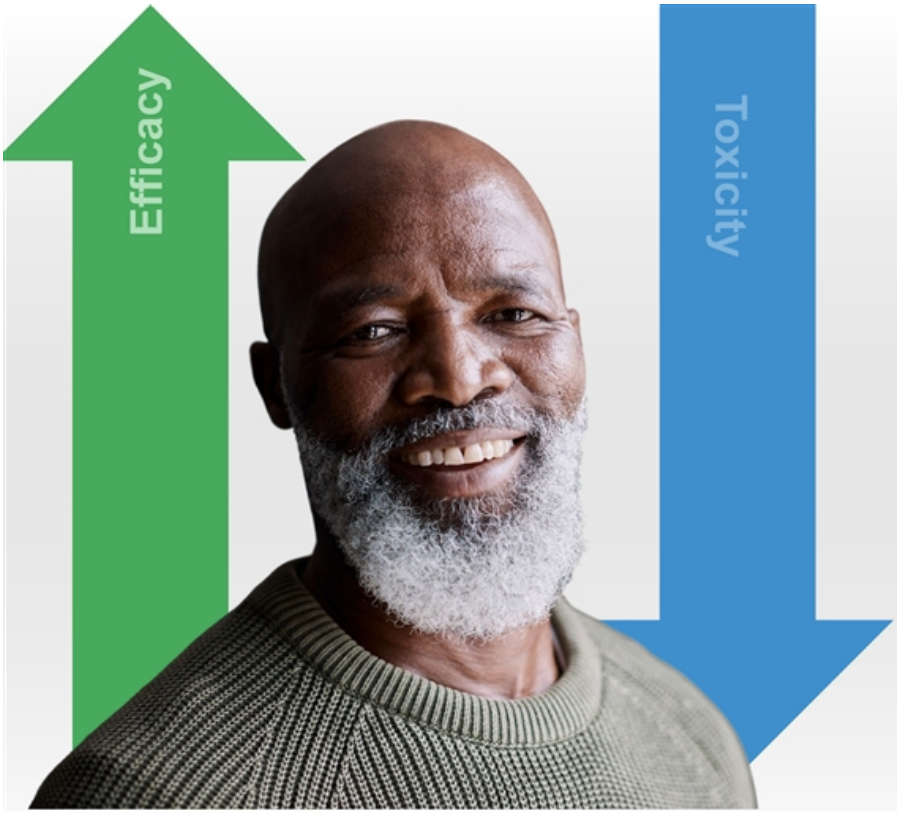
Forward-Looking Statements

Certain information contained in this presentation and statements made orally during this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and Galera's own internal estimates and research. While Galera believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. While Galera believes its internal research is reliable, such research has not been verified by any independent source.

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, the safety, efficacy, regulatory and clinical progress, and therapeutic potential of current and prospective product candidates, plans and timing for the commencement of and the release of data from clinical trials, our plans to prepare for commercialization and a US launch, the anticipated direct and indirect impact of COVID-19 on Galera's business and operations, planned clinical trials and preclinical activities, potential product approvals and related commercial opportunity, current and prospective collaborations, and timing and likelihood of success, plans and objectives of management for future operations, are forward-looking statements. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The information in this presentation, including without limitation the forward-looking statements contained herein, represent our views as of the date of this presentation. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. The forward-looking statements in this presentation involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the drug development process and the regulatory approval process, our reliance on third parties over which we may not always have full control, and other important risks and uncertainties that are described in Galera's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the U.S. Securities Exchange Commission (SEC) and Galera's other filings with the SEC. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

Whenever the Company uses the terms "transform radiotherapy" or "transforming radiotherapy" in this presentation, it is referring to its mission statement.



Transforming radiotherapy by **reducing side effects** and **increasing anti-cancer efficacy**

Over 50% of Cancer Patients Receive Radiotherapy

Toxicity

REDUCING TOXICITY

In radiotherapy Galera shifts the balance from normal tissue-damaging high levels of superoxide….

...WHILE INCREASING EFFICACY

to potentially
tumor-toxic
high levels of
hydrogen peroxide.

Transforming Radiotherapy

Reducing IMRT Toxicity

In Phase 3 with Breakthrough Therapy Designation

Severe Oral Mucositis
In Head & Neck Cancer

Esophagitis
in Lung Cancer

Increasing SBRT Efficacy

Encouraging Survival Data in Pancreatic Cancer Trial

Pancreatic Cancer
Locally Advanced

Lung Cancer
Locally Advanced

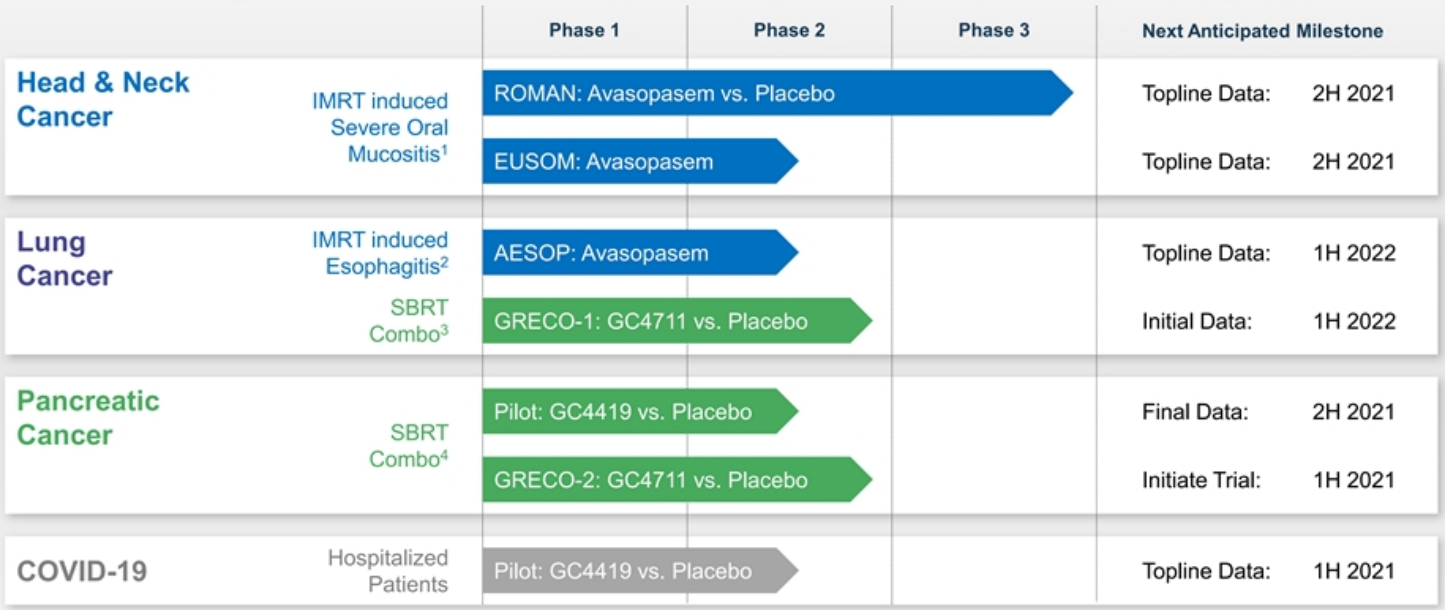
Large Market Opportunities

High Unmet Medical Need & Limited Therapeutic Options

Radiotherapy needed by over half of patients with cancer

Galera building US commercial team for Avasopasem Launch

Robust Pipeline



(1) EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe
(2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
(3) Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711
(4) The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial have been used to guide development of GC4711 to assess anti-cancer efficacy in combination with SBRT

Reducing IMRT Toxicity

Toxicity

Galera Therapeutics, Inc

223 Patient Phase 2b Trial – Robust Results

Randomized Placebo-Controlled Severe Oral Mucositis (SOM) Trial

Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks

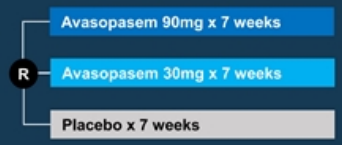
Treatment

- Avasopasem 90mg, 30mg, or placebo
- 60-minute IV infusion just before IMRT

Endpoints

- Primary: Reduction in SOM duration
- Secondary: Reduction in SOM incidence & severity

Randomized 1:1:1



Stratification

- Tumor HPV status: + / -
- Cisplatin schedule: qwk / q3wk

Tumor Outcomes

- Survival (OS, PFS)
- Locoregional control (LRC)
- Distant Metastases Free (DMF)

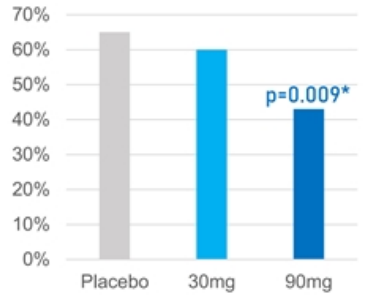
WHO Grading Scale:

Consistent and Encouraging Results

Across SOM Endpoints

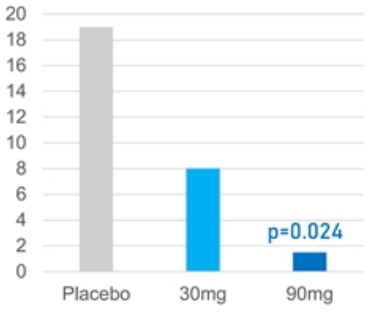
SOM Incidence

34% Reduction in incidence



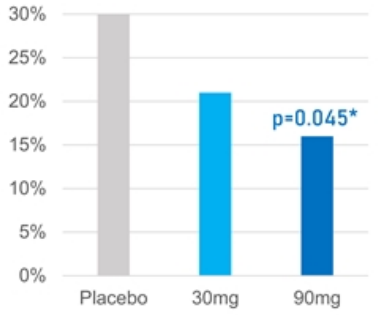
SOM Duration

92% Reduction in median days



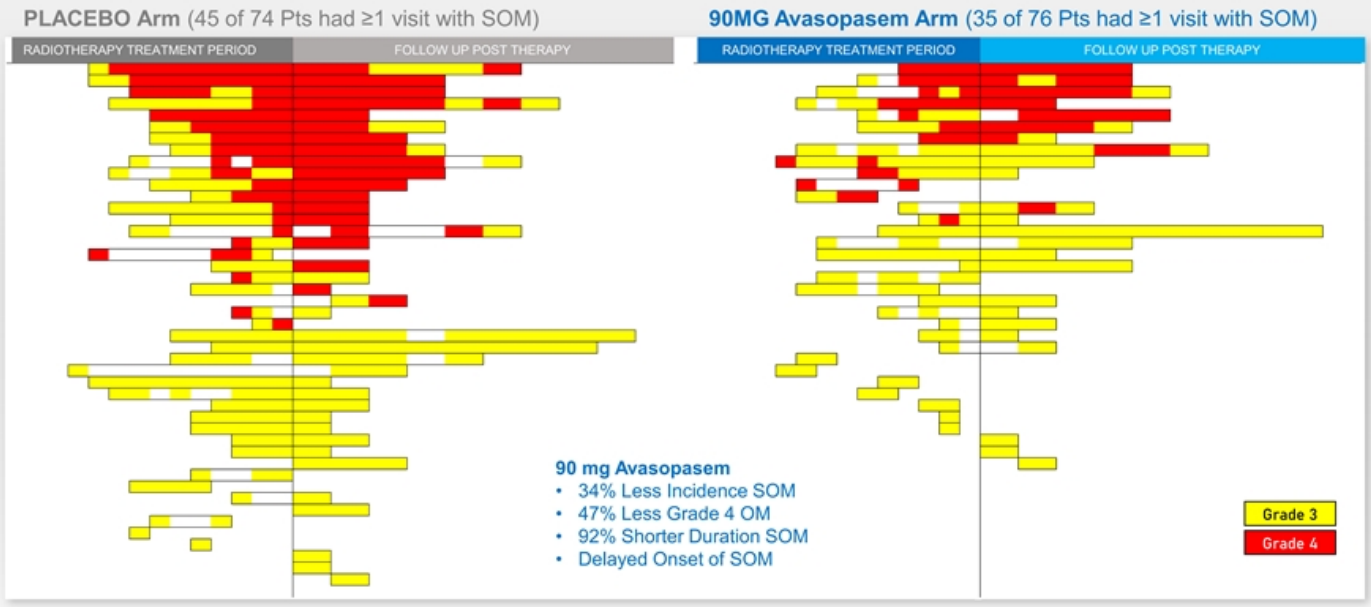
SOM Severity

47% Reduction in incidence of Grade 4

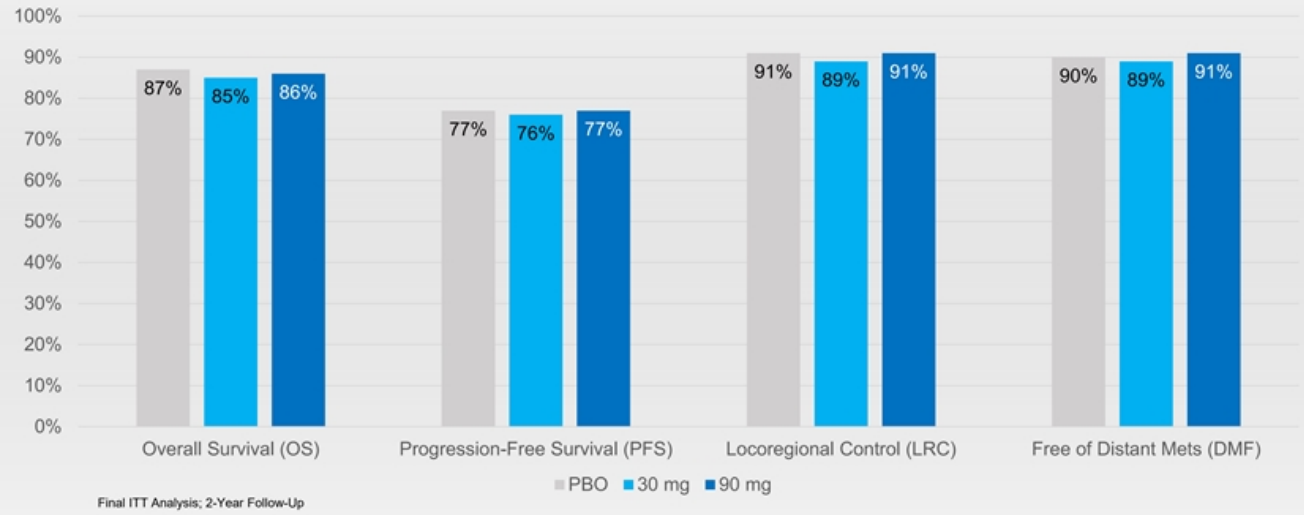


Intent-To-Treat (ITT) Population
*Secondary endpoints (incidence and severity) have nominal p values compared to placebo

Avasopasem Efficacy Significantly Better than Placebo



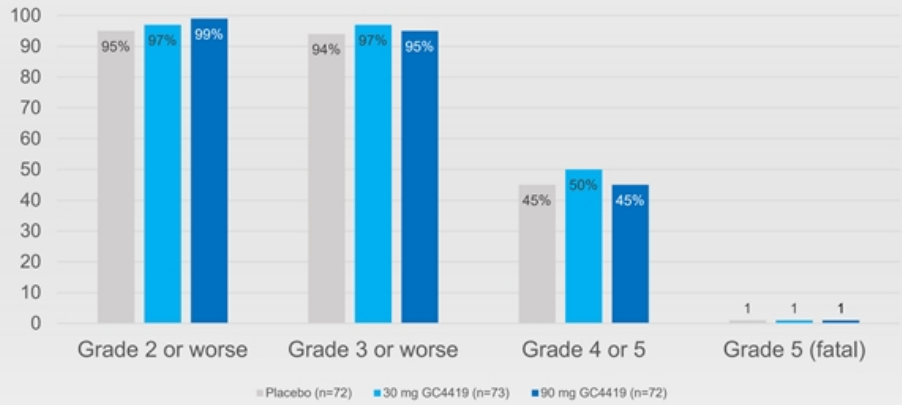
Radiotherapy Efficacy Results Maintained Over Two Years



Final ITT Analysis; 2-Year Follow-Up

Safety Results Comparable to Placebo

Avasopasem Generally Well Tolerated



Most Frequent AEs (any grade)	Placebo (n=72)	30 mg Avasopasem (n=73)	90 mg Avasopasem (n=72)
Lymphopenia	89%	92%	88%
Nausea	75%	68%	82%
Fatigue	69%	60%	65%
Oropharyngeal pain	64%	63%	61%
Constipation	53%	59%	64%
Radiation skin injury	47%	51%	53%
Vomiting	47%	52%	49%
Dysgeusia (taste)	49%	55%	43%
Dysphagia	43%	42%	47%
Weight decreased	35%	40%	44%
Oral candidiasis	29%	45%	43%
Leukopenia	39%	37%	39%

450 Patient Phase 3 Trial – Results this Year

Randomized Placebo-Controlled Severe Oral Mucositis Trial

Population

- Patients with Head & Neck Cancer (locally advanced)
- Receiving standard IMRT and cisplatin over 7 weeks

Treatment

- Avasopasem 90mg or placebo
- 60-minute IV infusion just before IMRT

Endpoints

- Primary: Reduction in SOM incidence
- Secondary: Reduction in SOM duration & severity

Randomized 3:2

R

- Avasopasem 90mg x 7 weeks
- Placebo x 7 weeks

Stratification

- Surgery status: + / - before Rx
- Cisplatin schedule: qwk / q3wk

Tumor Outcomes

- Survival (OS, PFS)
- Locoregional control (LRC)
- Distant Metastases Free (DMF)

WHO Grading Scale:

1	2	3	4
No ulcers Erythema & soreness	**Ulcers** Able to eat solid diet	**Ulcers** Require liquid diet	**Ulcers** Unable to eat or drink

SOM Market Opportunity

Galera Therapeutics, Inc

Head and Neck Cancer – Large Market Opportunity

Severe Oral Mucositis is most burdensome side effect – 70% get SOM

650,000
Global Head & Neck Cancer Incidence

65,630
US Patients Diagnosed each year

42,000
US Patients at Risk for RT-related SOM

Locally advanced HNC curable with the standard-of-care IMRT and cisplatin regimen

Head and Neck Cancer Can Affect Anyone

Babe Ruth, Lana Turner, Jamie Dimon, Ulysses S. Grant, Sigmund Freud, Humphrey Bogart, Grover Cleveland, Eddie Van Halen
Sammy Davis Jr., George Harrison, Michael Douglas, Ann Richards, Tony Gwynn

Avasopasem: First-to-Market Potential

Current Approaches Lack Efficacy

MAASC Guidelines focus only on symptoms[1]

- Basic Oral care
- Opioids, anesthetics
- Coating agents
- Benzydamine
- Anti-inflammatories

Rad Oncs Consider Topicals Ineffective

Market Research with 150 Radiation Oncologists[2]

- Only 20% of physicians believe topical agents perform well for oral mucositis

Avasopasem is Disease Modifying

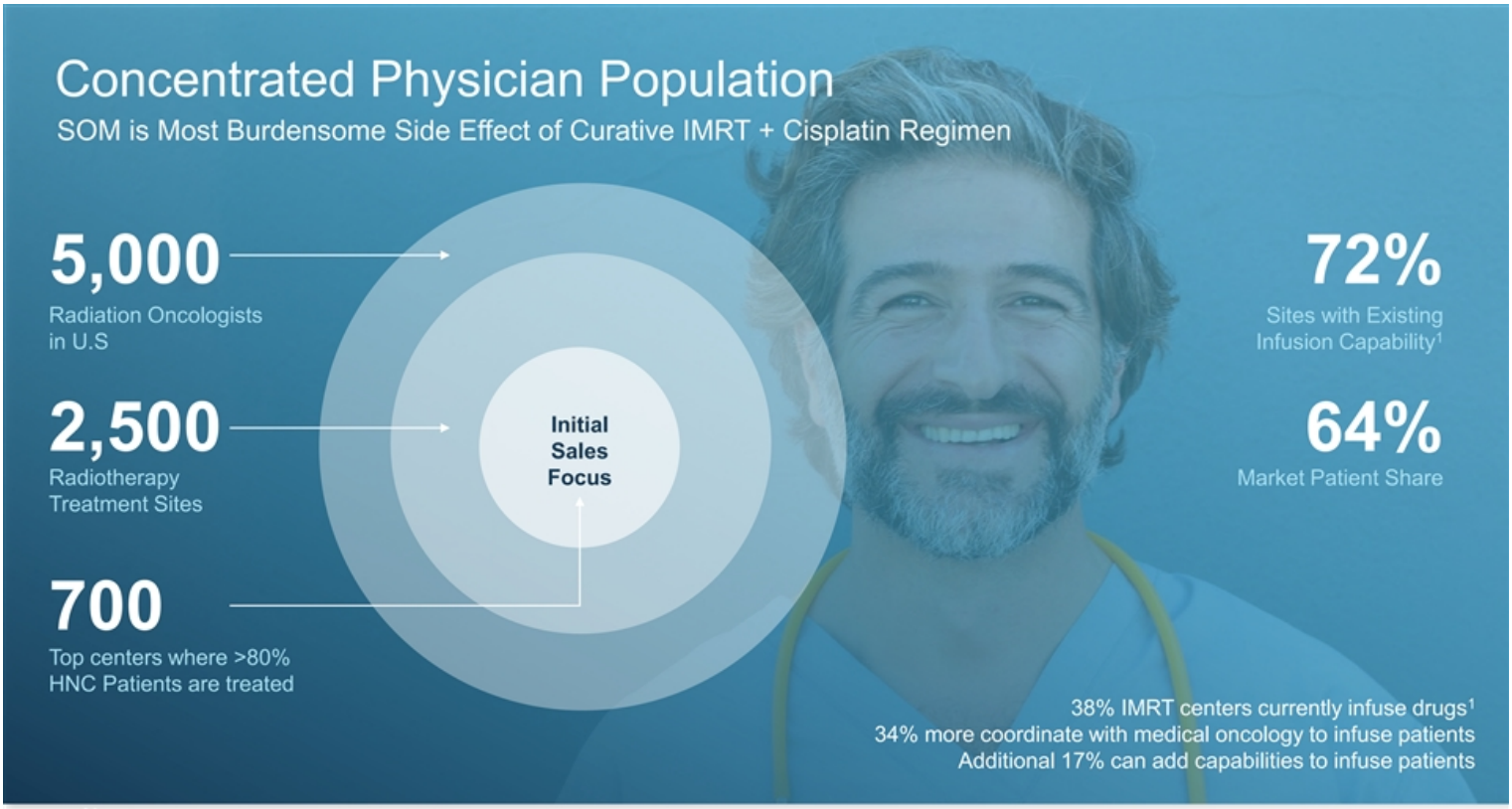
Only Breakthrough Therapy Designation for SOM[3]

- Consistent and encouraging results across SOM endpoints
- Largest Phase 3 Trial
- Data anticipated in 2021

[1]Elad S et al, MASCC/ISOO Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. Cancer 2020;126:4423-4431
[2]Galera Market Research
[3]FDA breakthrough therapy designation received for avasopasem for reduction of SOM induced by radiotherapy, with or without systemic therapy

Concentrated Physician Population

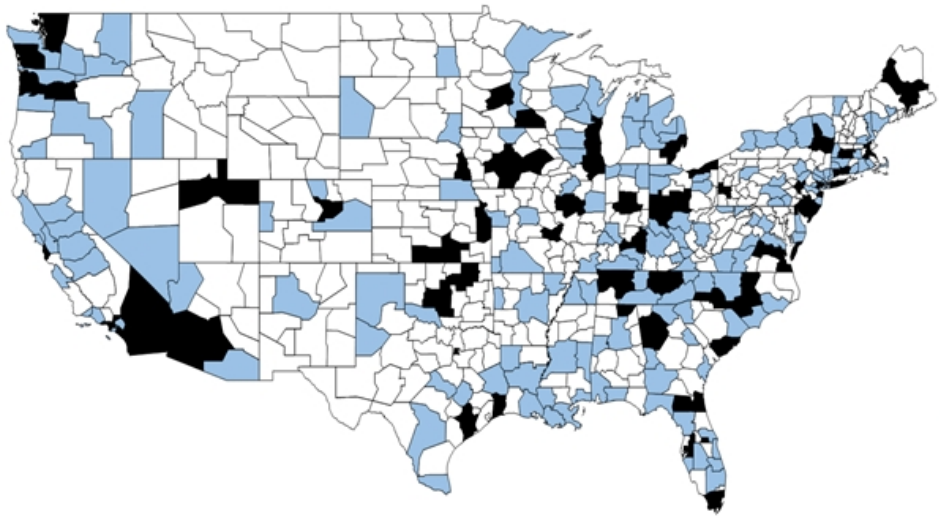
SOM is Most Burdensome Side Effect of Curative IMRT + Cisplatin Regimen



[1]Primary market research with 125 IMRT centers in the US

Where Patients with Head & Neck Cancer are Treated

76% Treated in only 29% Zip Code Areas



3-Zip Code Counts		Cases	
>104	72	16,701	58%
>53	141	21,786	76%
≤53	348	6,787	24%
	489	28,573	

Galera Market Research (122 Zip Codes are 0)

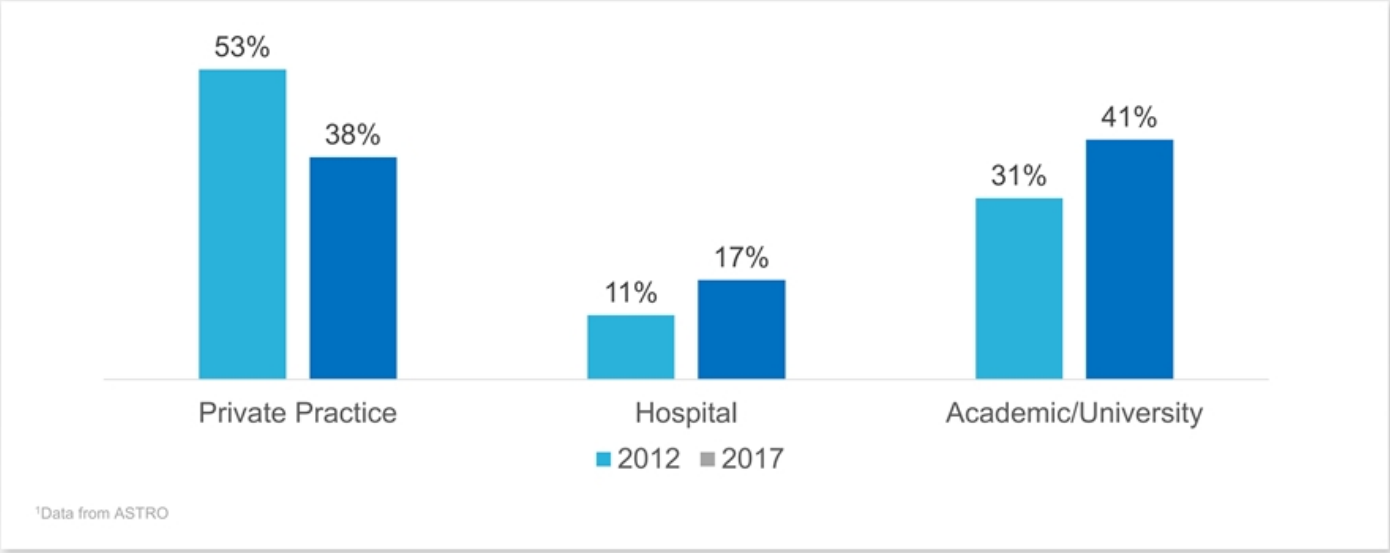
Most IMRT Centers Have Ability to Infuse Today

72% Radiotherapy Sites Have Existing Infusion Capability

Adoption Archetype Determinants	A Rad Oncs Have Current Capabilities	B Med Oncs Administer Infusions for Rad Onc	C Rad Oncs Need to Add Capabilities	D Rad Oncs Unlikely to Add Capabilities
Avasopasem Infusion Owner	Rad Onc	Med Onc	Rad Onc	-
MD-Stated Patient Volume	**High**	Low	**High**	Moderate
Ease of Coordination Today	**High**	**High**	Low	Low
Likelihood of Prescribing Avasopasem	**High**	**High**	**High**	Low
Total % Sample Distribution (n)	38% (51)	34% (39)	17% (23)	11% (12)

Data in above table based on primary market research with 125 IMRT centers in the US

US Radiation Oncologists Trending Away from Private Practice



[1]Data from ASTRO

Favorable Payer Landscape

$40,000

Additional medical expenses incurred by patients who develop OM

$15-25K

Indicative price of full course of therapy based on initial payer research

Price strategy intended to optimize patient access

Head and neck cancer not a focus for cost control measure

Step Edits Unlikely

High unmet need with limited treatment options

Esophagitis in Lung Cancer

50% patients get Grade 2 or worse

2,500,000
Global NSCLC Incidence

175,000
US Patients Diagnosed each year

50,000
US Patients at Risk for RT-related Esophagitis

Locally advanced NSCLC frequently treated with IMRT and chemotherapy

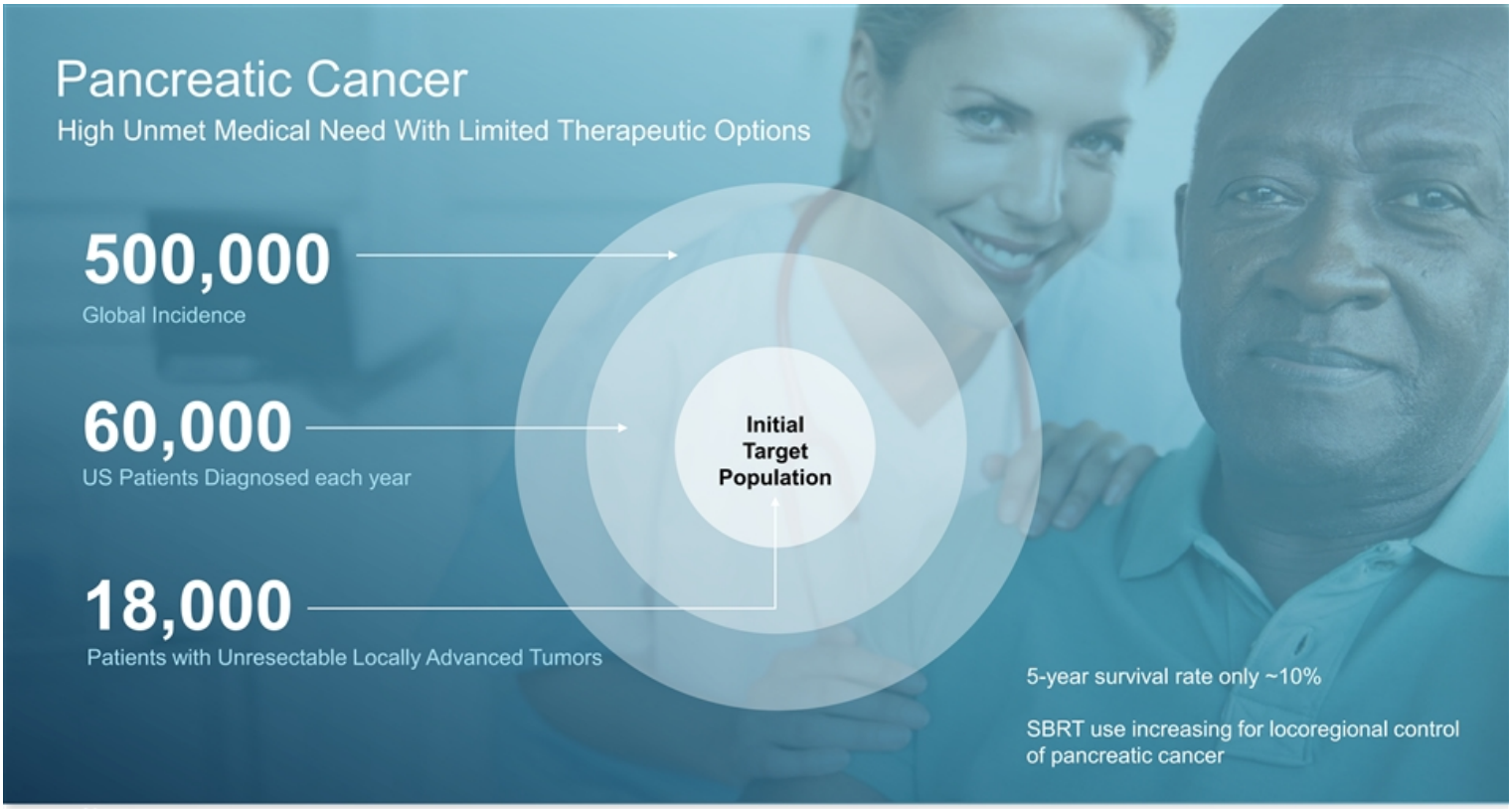

Increasing
SBRT Efficacy
Efficacy
Galera
Therapeutics, Inc

People we Have Lost to Pancreatic Cancer

Pavarotti, Donna Reed, Dizzy Gillespie, Cardinal Bernardin, Eiko Ishioka, Bonanza's Pernell Roberts, Joan Crawford
Ben Gazzara, Alex Trebek, Alan Bates, Jack Benny, Dr. Sydney Salmon, Billy Paul, Rand Pausch (last lecture)
Ruth Bader Ginsburg, John Lewis, Henry Mancini, Sally Ride, Munster's Fred Gwynne, Columnist William Safire, Michal Landon

Pancreatic Cancer

High Unmet Medical Need With Limited Therapeutic Options



5-year survival rate only ~10%

SBRT use increasing for locoregional control of pancreatic cancer

Pilot Trial in Pancreatic Cancer

42-Patient Double-blind, Placebo-controlled, Randomized Trial

Population

- Patients with Locally-advanced Pancreatic Cancer (LAPC)
- Enrolled after 4-6 months of chemotherapy

Treatment

- High-Dose Stereotactic RT (SBRT) 10-11Gy x 5 doses
- 60-minute IV infusion of 90mg GC4419 or placebo

Endpoints

- Safety and Feasibility of dismutase mimetic with SBRT
- Survival (OS, PFS)
- Response Rate
- Tumor Control (DMC, LRC)

Design

R

- SBRT + GC4419 90mg x 5 doses
- SBRT+ Placebo x 5 doses

42 Patients

	Single Center	Multi Center
Placebo	N=8	N=10
GC4419	N=11	N=13
	>1 Year Follow-Up	>6 Months Follow-Up

Enrolling Centers

- MD Anderson, Houston, TX
- Moffitt Cancer Center, Tampa, FL
- UT Southwestern, Dallas, TX
- Duke University, Durham, NC

Highlights of Current Analysis

Follow-up through at least 6 months on all patients

85% Increase in Overall Survival

Survival

Median Overall Survival

GC **20.1 Mos**

PBO **10.9 Mos**

2.5-fold Increase in Response Rate

Response

Partial Response Rate

GC **29%**

PBO **11%**

2-fold Increase in Time to Metastases

Metastases

Median Time to Mets

GC **13.9 Mos**

PBO **7.0 Mos**

Median follow-up of 9 months as of this data analysis (maximum follow-up 32 months)

Surgical Resection

- 5/24 on GC
  All with clear tumor margins
- 2/18 on PBO
  1 with clear tumor margins

Hazard Ratios (GC vs. PBO)

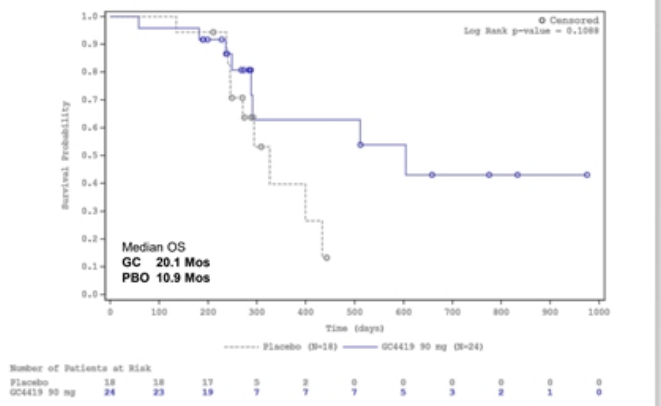
OS	0.4
PFS	0.4
LRC	0.3
DMC	0.3

OS = Overall Survival
PFS = Progression-Free Survival
LRC = Locoregional Control
DMC = Control of Distant Metastases

Median Overall Survival Increased 85%

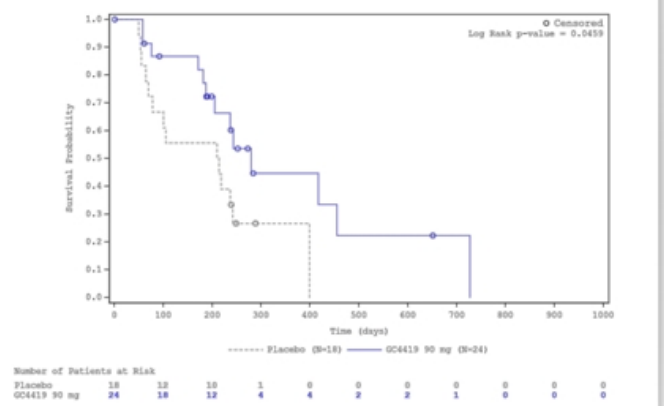
Encouraging hazard ratios for both OS and PFS

Overall Survival (OS)



Hazard Ratio = 0.4

Progression-Free Survival (PFS)[1]

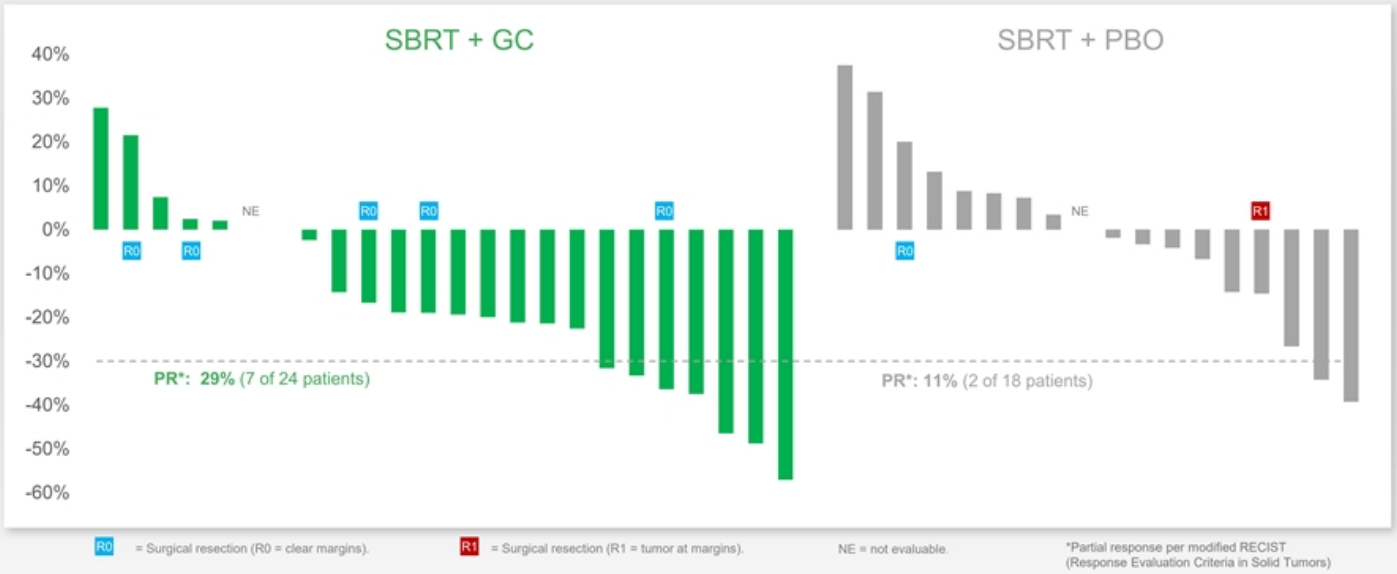


Hazard Ratio = 0.4

[1]*PFS defined as local progression or distant metastasis; not censored for treatment post SBRT*

Partial Response Rate Increased 2.5-fold

Best Local Response with follow-up through at least 6 months on all patients (ITT, n=42)



R0 = Surgical resection (R0 = clear margins).

R1 = Surgical resection (R1 = tumor at margins).

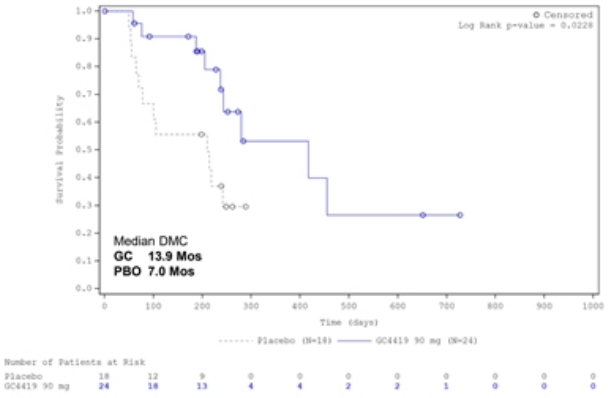
NE = not evaluable.

*Partial response per modified RECIST (Response Evaluation Criteria in Solid Tumors)

Time to Distant Metastases Increased 2-fold

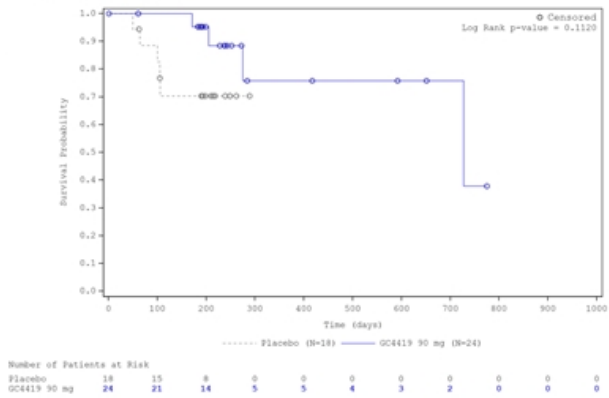
And Improved Locoregional Control

Distant Metastases Control
– outside RT Field



Hazard Ratio = 0.3

Locoregional Control (LRC)
– within RT Field



Hazard Ratio = 0.3

Patients censored for cancer progression or death (not for consolidation treatment post SBRT if no progression)

Regimen Generally Well Tolerated

Toxicity reports through first 90 days after SBRT (ITT, n=42)

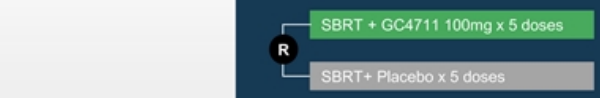
Acute Adverse Events (up to 90 days post SBRT)	Placebo (n=18)	Avasopasem (n=24)
Grade 3+ AEs	4 (22%)	6 (25%)
Grade 3 Gastrointestinal AEs[1]	2 (11%)	2 (8%)

[1]No bleeding ulcers by 12-week endoscopy, no GI toxicity > Grade 3

Next Steps

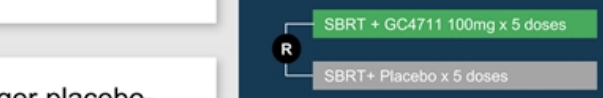
Proof of Concept	Efficacy results from blinded controlled trial consistent with preclinical studies that showed synergy with RT
Consistent Synergy	Magnitude of synergy with RT and consistency across efficacy parameters is very encouraging
GRECO Trials	Galera advanced its dismutase mimetics into larger placebo-controlled trials, in pancreatic and lung cancer

GRECO-1



- Placebo-controlled multicenter trial
- Locally Advanced NSC Lung Cancer – large & central tumors
- 71 Patients
- Status: Open & Recruiting Patients

GRECO-2



- Placebo-controlled multicenter trial
- Locally Advanced Pancreatic Cancer – following neoadjuvant chemotherapy
- 160 Patients
- Status: Soon to open to enrollment

SBRT for Non-Small Cell Lung Cancer

SBRT is an established treatment for central and large peripheral NSCLC tumors

2,500,000
Global NSCLC Incidence

175,000
US Patients Diagnosed each year

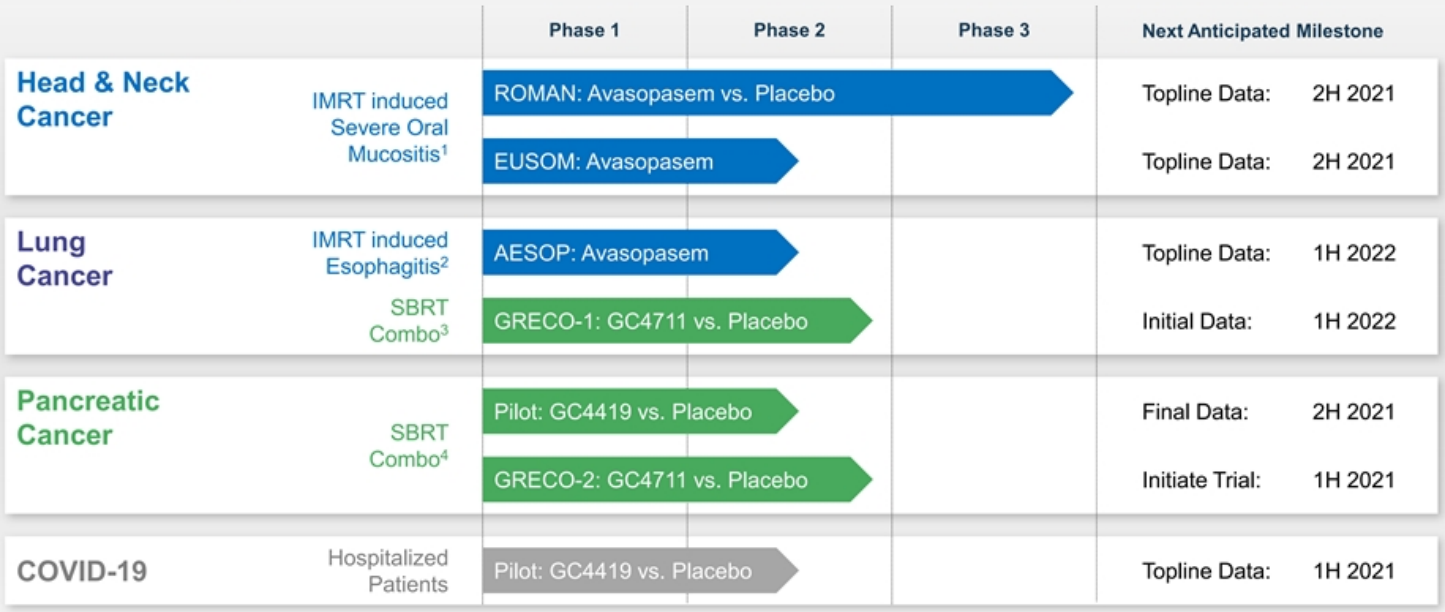
55,100
Node-Negative NSCLC

All SBRT	14,600	12,120	15,430
Node-Negative NSCLC	Peripheral Tumor >3cm	Central Tumor <3cm	Central Tumor >3cm
Surgery ONLY	16%	30%	12%
SBRT (+/- other modalities)	81%	67%	85%
Other	3%	2%	4%

Corporate Highlights

Galera Therapeutics, Inc

Robust Pipeline



(1) EUSOM is a single-arm multi-center trial evaluating the safety and efficacy of avasopasem in patients with HNC in Europe
(2) Phase 2a trial in patients with lung cancer building on avasopasem safety and tolerability findings from SOM trials in patients with HNC
(3) Trial to assess anti-cancer efficacy of SBRT +/- GC4711; subsequently, intend to assess anti-cancer efficacy of SBRT and checkpoint inhibitor +/- GC4711
(4) The first SBRT combination trial used GC4419 (avasopasem). Observations from this pilot trial have been used to guide development of GC4711 to assess anti-cancer efficacy in combination with SBRT

Back-up Slides

Mechanistic and Preclinical Data

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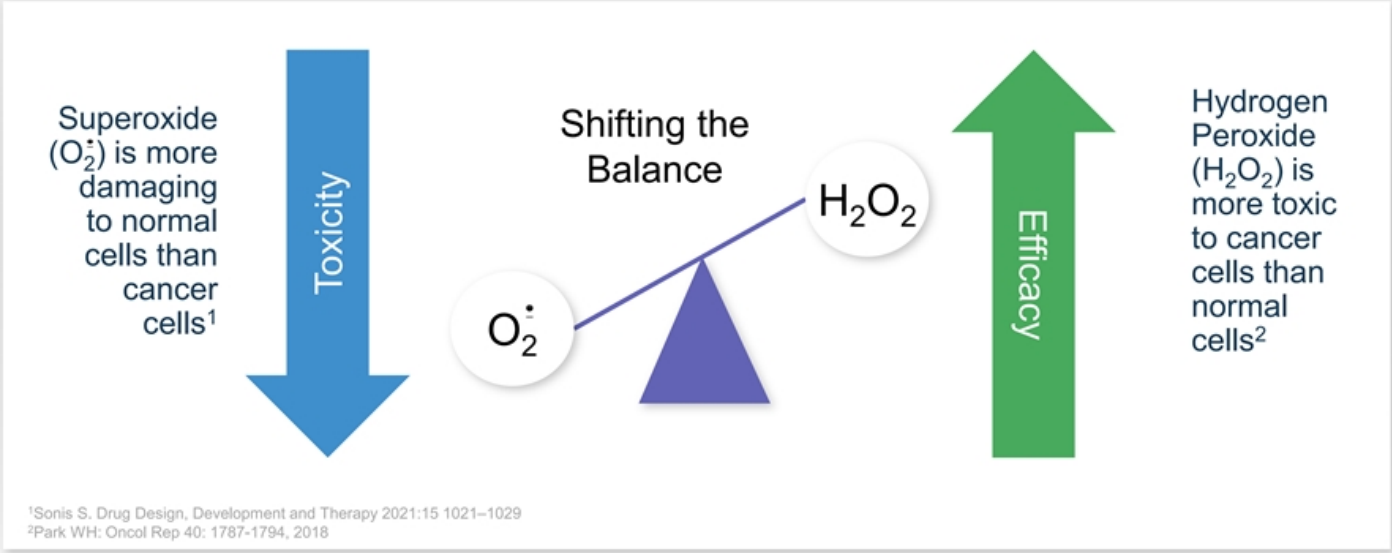
Differential Effect of Dismutase Mimetics

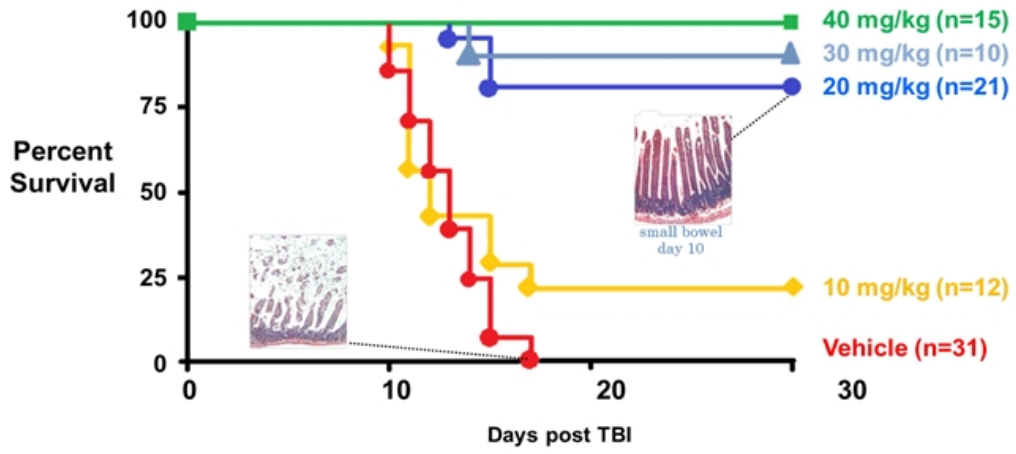
Conversion of superoxide to hydrogen peroxide leverages inherent tissue differences



[1]Sonis S. Drug Design, Development and Therapy 2021:15 1021–1029
[2]Park WH: Oncol Rep 40: 1787-1794, 2018

Protection from Lethal Radiation Exposure

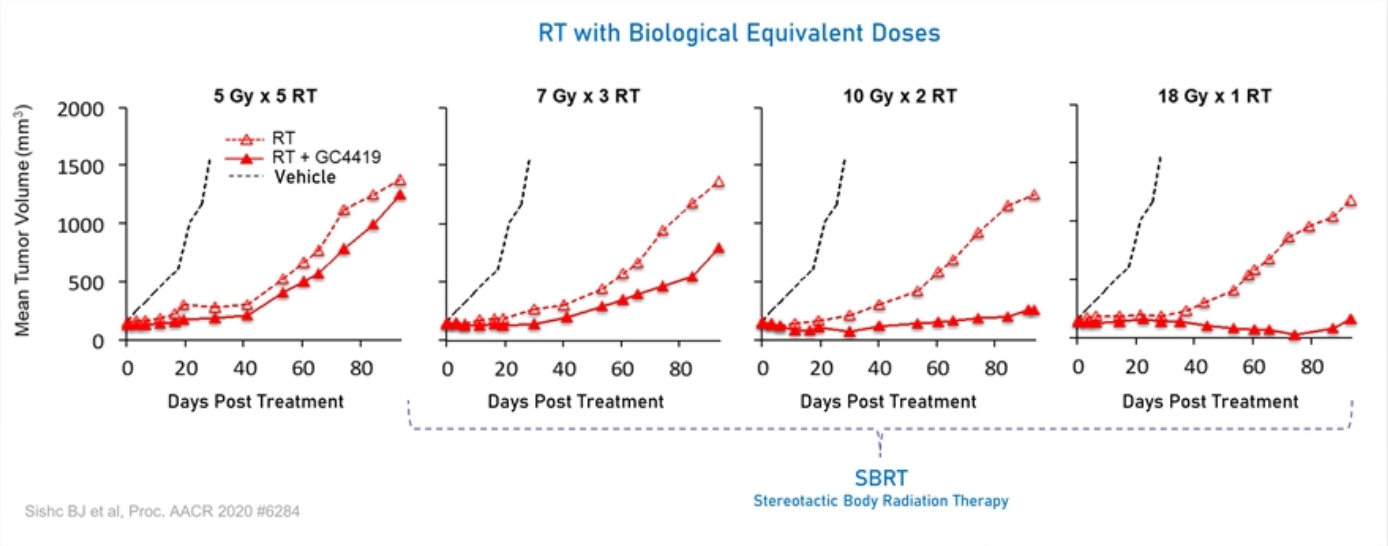
Observed in Preclinical Studies – Total Body Irradiation (8.5 Gy) to Mice



Thompson, et al., Free Radical Research, 44(5):529-540, 2010

Synergy with High-Dose RT (SBRT)

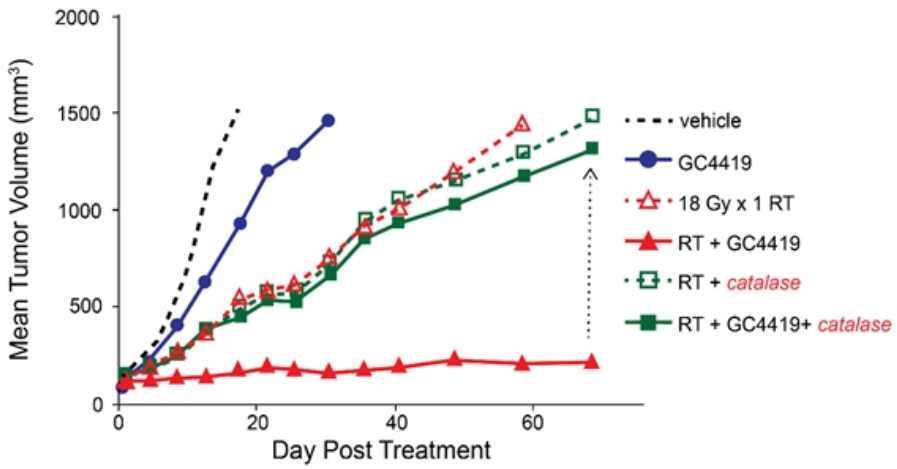
High-fraction focal irradiation of human tumor xenografts (H1299 NSCLC) in mice



Sishc BJ et al, Proc. AACR 2020 #6284

H_2O_2 build-up in Cancer Cell → Synergy with SBRT

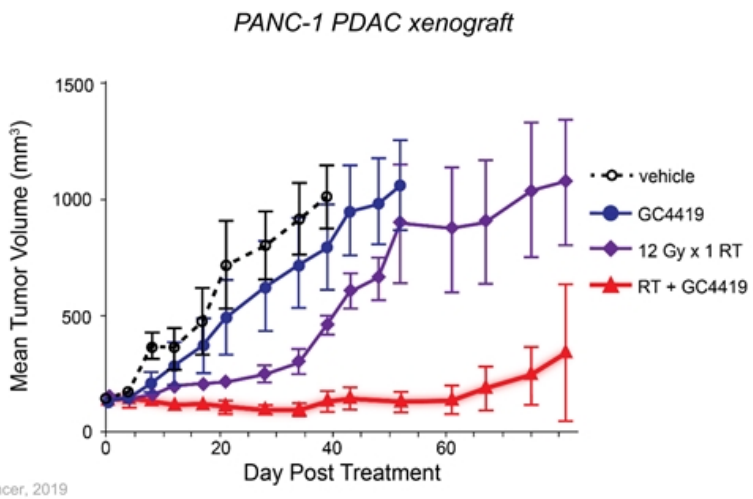
Synergy abrogated with doxycycline-induced catalase in genetically modified $H1299^{CAT}$ cells



Sishc BJ et al, AACR, 2018

Pancreatic Tumor Model → Synergy with SBRT

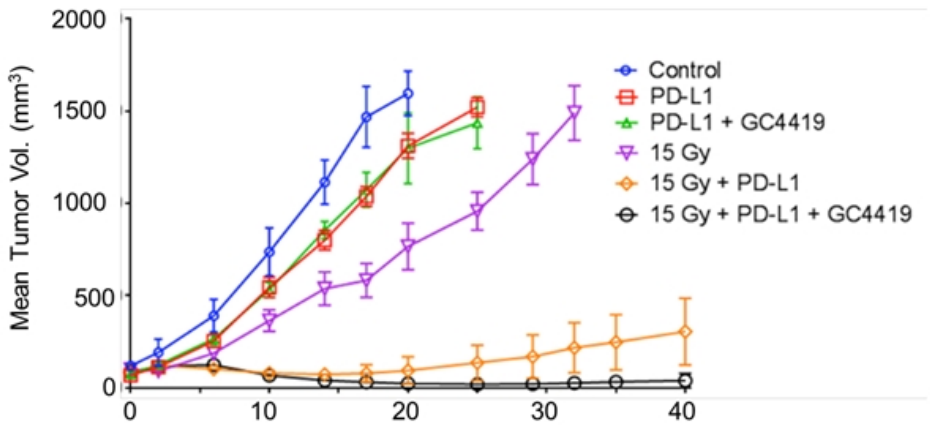
Marked synergy of Dismutase Mimetic with 12 Gray Radiotherapy



Sishc BJ et al, AACR Pancreatic Cancer, 2019

Enhanced Checkpoint Inhibitor Activity in Vivo

GC4419 enhanced tumor response to SBRT + anti-PD-L1, PD-1 or CTLA-4 – within and outside RT field



Galera Data on file